(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 332 330 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 89302006.5

(51) Int. Cl.[4]: A61M 5/14

(22) Date of filing: 28.02.89

(30) Priority: 08.03.88 US 165619

(43) Date of publication of application:
13.09.89 Bulletin 89/37

(84) Designated Contracting States:
DE FR GB

(71) Applicant: BAXTER INTERNATIONAL INC. (a Delaware corporation)
One Baxter Parkway
Deerfield Illinois 60015(US)

(72) Inventor: Bobo, Donald E., Jr.
246 N Bobwhite Way
Orange California 92669(US)
Inventor: Seguine, Dennis R.
23552 Via Calzada
Mission Viejo California 92692(US)
Inventor: Lapp, Theodore R.
28001 Cascabel
Mission Viejo California 92692(US)

(74) Representative: MacGregor, Gordon et al
ERIC POTTER & CLARKSON 14 Oxford Street
Nottingham, NG1 5BP(GB)

(54) Automatic infiltration dectection system and method.

(57) An infusion system for infusing a fluid into a patient comprising an infusion device for delivering the fluid in both a normal delivery pattern and a test pulse and a conduit for conducting the fluid from the infusion device to the patient. The test pulse creates a pressure wave response in the conduit. Abnormal infusion can be detected by determining the area between a baseline and at least a portion of a pressure versus time curve representing the pressure wave response.

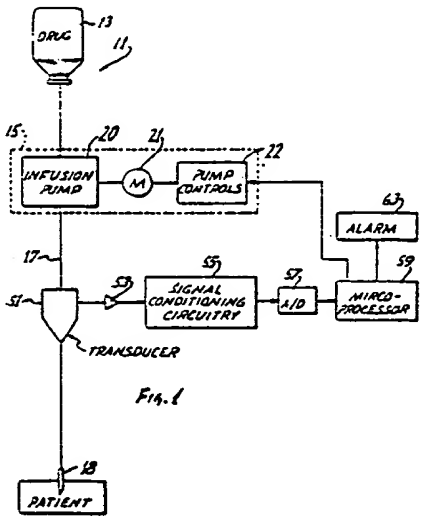

Fig. 1

EP 0 332 330 A2

AUTOMATIC INFILTRATION DETECTION SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

It is often necessary or desirable to infuse a flowable material or fluid, which may be liquid, a gas or a combination thereof, into a patient. One example is the administration of parenteral fluids to a patient.

A typical infusion system includes an infusion device for delivering the fluid and conduit means for conducting the flowable material from the infusion device to the patient. The conduit means typically comprises flexible tubing leading from the infusion device and a cannula, such as a needle or catheter, for insertion into the vascular system of the patient. In normal operation, the infusion device delivers the fluid through the tubing and the needle to the vascular system of the patient.

One problem with infusion systems of this type is a condition known as infiltration. Infiltration is a condition in which infused fluid finds its way into extravascular tissues rather than simply being released into the blood stream. Such a situation occurs when the needle is not in communication with the interior of the vessel into which the fluid is to be infused. When this occurs, fluid is infused into the interstitial spaces between layers of tissues. Thus, the patient is deprived of proper intravenous drug administration and is further subjected to possible toxic or caustic effects associated with infused fluids being in direct contact with body tissues.

Infiltration is not the only possible type of anomaly associated with intravenous therapy which can cause the fluid to be improperly supplied to the patient. Other conditions which can cause abnormal infusion, i.e., the fluid to be improperly supplied to the patient, include venous inflamation and swelling at the infusion site (phlebitis), clotting and a wide variety of obstructions of the conduit means, such as kinking of the tubing which supplies the fluid to the patient. Many of these affect fluid flow characteristics in a manner similar to infiltration and can, therefore, be detected by infiltration detection devices.

The goal of an infiltration detection system is to identify an abnormal infusion as early as possible without generating an excessive number of false alarms. Early detection allows the attending medical staff to rectify the problem before significant damage has been done by the infiltration and before the patient has been deprived of a significant amount of the intravenous therapy. On the other hand, if the detection system is too sensitive, false alarms will result. This is very undesirable since, from a clinical perspective, establishing a new intravenous site can be difficult and time consuming. During the time necessary to start the new IV, which can be hours in some cases, the patient is not receiving the desired treatment.

Bobo U.S. Patent No. 4,648,869 discloses a significant advance in the field of infiltration detection systems and methods. According to the Bobo patent, an infusion system infuses a test pulse of fluid to a patient. The test pulse creates a pressure wave response which can be monitored and used to detect if abnormal infusion has occurred.

Butterfield U.S. Patent No. 4,710,163 discloses an infiltration detection system which uses the test pulse-pressure wave response concept of the Bobo patent. However, the Butterfield system compares the pressure wave response with a reference pressure wave response which represents the normal response when there is no infiltration. Specifically, the area between two curves representing these responses is used to attempt to detect infiltration. Thus, the Butterfield approach has the disadvantage of requiring that a normal pressure wave response be first determined and then stored for later comparison.

SUMMARY OF THE INVENTION

This invention provides a novel and improved technique for detecting abnormal infusion, i.e., if fluid is being improperly supplied to a patient. To make this determination, this invention utilizes the area between a baseline and at least a portion of a pressure versus time curve which represents the pressure wave response. With this technique, it is not necessary to first establish a normal pressure wave response for a patient, nor is it necessary to compare this assumed normal response to the pressure wave response. Rather, with this invention, all that is required to make accurate determinations as to the proper supply of fluid to a patient is appropriate area information from the pressure wave response.

This invention provides an apparatus for determining if fluid is being properly supplied through a fluid delivery system to a patient, and such apparatus includes means for delivering fluid through the delivery system so as to create a pressure wave response in the delivery system. This may be accomplished, for

example, in accordance with the teachings of Bobo U.S. Patent No. 4,648,869, which is incorporated by reference herein. Thus, as disclosed in the Bobo patent, the fluid may be delivered in both a normal delivery pattern and a test pulse, with the test pulse creating a pressure wave response in the delivery system.

The apparatus also includes means for determining the area between a baseline and at least a portion of a pressure versus time curve which represents the pressure wave response, and means responsive to the magnitude of such area for detecting if the fluid is being improperly supplied by the fluid delivery system to the patient.

The pressure wave response has a peak value of pressure and a leading portion and a trailing portion on opposite sides of the peak value. When fluid is being properly supplied to the patient, the pressure will rise rapidly but typically not to a very high peak value. However, if the fluid is being improperly supplied to the patient as when infiltration occurs, the pressure will rise to a higher peak value over a longer period of time. The peak pressure is large because the infused fluid has no immediate means of escape from the interstitial spaces. After termination of the test pulse, the pressure will drop rapidly to its nominal level if the fluid is being properly supplied to the patient. In the case of abnormal infusion, the pressure drops much more slowly from the peak value because there is no immediate escape path for the fluid.

The integration technique of this invention uses an area characteristic of the pressure wave response to determine if fluid is being improperly supplied to the patient. The function integrated is the difference between a baseline and a curve representing the pressure wave response and extends along the curve from an initial point to a truncation point. Although the baseline can be established in different ways, preferably, the baseline is established as a function of the pressure in the delivery system when the test pulse and, hence the pressure wave response, are not present. The baseline used for the integration is preferably held essentially constant during the integration.

The truncation point, or upper limit on the integration, preferably is on the trailing portion of the curve corresponding to the trailing portion of the pressure wave response, i.e., it preferably occurs after the peak value of pressure has been attained. Although it is possible to truncate the integration prior to or at the peak value of pressure, because the peak pressure is typically drastically different when the fluid is being improperly supplied to the patient, it is highly desirable to include, and go beyond, the peak value for the integration.

The output from an infusion pump used to deliver the fluid to the patient may not be totally uniform, and preferably, the truncation point occurs at a time which is sufficiently beyond the peak value of pressure so as to take this into account. Typically, it is preferred that the truncation point be at a time at which the pressure is no greater than about 70 percent of the peak value.

On the other hand, the truncation point is preferably essentially outside of the noise range, and this typically means that it occurs at a time at which the pressure is no less than about 30 percent of the peak value. Thus, the truncation point is preferably at a time at which the pressure is between about 30 and about 70 percent of the peak value with about 50 percent being considered optimum. The initial point, or lower limit on the integration, is preferably essentially at the beginning of the point on the curve corresponding to the beginning of the pressure wave response.

Alternatively, or in addition thereto, the integration of the pressure wave response may extend from the initial point to about the peak value of pressure. Such an integration would determine a front end area. The detecting means may be responsive to either or both of the front end area and the truncated area, i.e., the area established by integrating the pressure wave response from the initial point to the truncation point. Preferably, the detecting means is responsive to both of these areas.

The infusion device should be capable of delivering the fluid in a test pulse. Broadly, it is only necessary that the test pulse be capable of creating a pressure wave response in the delivery system. Typically, to accomplish this, the test pulse must be distinguishable from the normal deliver pattern.

The test pulse can be distinguished from the normal delivery pattern in different ways. For example, the test pulse can be separated from the normal delivery pattern by separating regions on one or both sides of the test pulse, with each of the separating regions providing a different flow rate of fluid than the adjacent portions of the test pulse. In a broad sense, the separating regions may have flow rates equal to the flow rate of the normal delivery pattern. Preferably, however, the infusion device is capable of delivering the fluid in an altered pattern which includes a test pulse and leading and trailing valleys on opposite sides of the test pulse. The test pulse provides a greater flow rate of fluid than the normal delivery pattern, and each of the valleys provides a lesser flow rate of fluid than the adjacent portions of the normal delivery pattern. When this form of infusion is used, the truncation point is preferably established as the first to occur of a specified percent of peak value and the termination of the trailing valley. This is desirable because, in the case of infiltration, where the pressure wave response decays slowly, the predetermined pecent of peak

value may not be reached. With this form of infusion, the initial point may coincide with the beginning of the test pulse.

The flow rate during the test pulse may be less than, greater than, or equal to the flow rate during the normal delivery pattern. However, the preferred altered pattern, as described above, has several advantages, including the advantage of preventing the test pulse from significantly altering the average flow of fluid to the patient. It is also possible to reverse the flow in the delivery system to create the test pulse. However, this is not preferred because it may cause the patient's vessel to collapse arond the needle.

The area information from the test pulse can be processed in various different ways to determine if the fluid is being properly or improperly supplied to the patient. Generally, a larger area indicates an alarm condition, and a smaller area is indicative of normal infusion. The areas are also a function of test pulse infusion rates. Of course, information from multiple pressure wave responses derived from multiple test pulses can be processed to gain greater assurance that the infusion system is being correctly monitored.

Another important feature of this invention is ascertaining if the pressure conditions in the conduit are suitable for detecting abnormal infusion. It has been found that the occurrence of a baseline pressure during the normal delivery patter which is unusually large in magnitude or which fluctuates excessively, suggests that the pressure conditions in the conduit are not then suitable for detecting abnormal infusion. Such baseline conditions may be the result of a transient condition, such as movement by the patient. When these pressure artifacts occur, either the application of the test pulse is deferred or the data derived from such test pulse is ignored.

The presence of these unacceptable pressure disturbances in the baseline indicate that the pressure conditions are not suitable for detecting abnormal infusion, and one reason for this is that these pressure artifacts would be superimposed upon the pressure wave response. This would tend to unacceptably alter the pressure wave response such that the pressure wave response wold not be indicative of the health of the IV site, but rather indicative of some other condition, such as unusual patient movement. This feature of the invention is applicable to virtually any abnormal infusion detection system, which is responsive to the pressure wave response, and is not limited to use with a system which detects abnormal infusion by integration techniques.

More specifically, the suitability of the pressure conditions in the conduit can be determined by comparing a function of the pressure of the fluid in the conduit during the normal delivery pattern to a threshold. This function of the pressure may be one or more pressure values or may be a function which is derived from one or more pressure values. In a preferred technique, the function of the pressure equals $B1 + K(B2)$ where B1 is the baseline pressure at an instant prior to the test pulse, K is a constant, and B2 is the rms value of a plurality of segments of the baseline pressure prior to the test pulse, and with at least one of the segments being prior to such instant.

The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying illustrative drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a block diagram illustrating one form of infusion system constructed in accordance with the teachings of this invention.

Figs. 2-2E are plots of volume delivered by the infusion device versus time illustrating different examples of test pulses.

Fig. 3 is a plot showing one pressure wave response indicative of the fluid being properly supplied to the vessel of a patient and a second pressure wave response indicative of infiltration.

Fig. 4 is a plot showing the relationship of the pressure response to the infusion rate for infiltration conditions and normal conditions.

Fig. 5 is a flow chart showing how the system functions to detect infiltration.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Fig. 1 shows an infusion system 11 which comprises a source 13 of a parenteral fluid, an infusion device 15 for delivering the parenteral fluid through conduit means 17 to a patient. The conduit means 17 may comprise flexible tubing or other flow channels for supplying the parenteral fluid to the patient. The

conduit means terminates in a needle 18, such as an I.V. needle, which is adapted to be inserted into a vessel of the patient's vascular system so that the open distal end of the needle communicates with the interior of the vessel. In this embodiment, the needle 18 is inserted into a vein. If the open distal end of the needle communicates with tissue, as when the needle is forced completely through the vessel wall, infiltration has occurred.

The infusion device 15 may be any infusion device which is controllable to produce a test pulse 19 (Fig. 2) and, as such, may include an infusion pump, a controller, syringe or the like. In this embodiment, the infusion device 15 includes a motor, such as a stepping motor 21, for driving the pump and pump controls 22 for controlling the motor. The pump 20 is a positive displacement pump, and accordingly, its output can be controlled by controlling the speed of the motor 21. The pump controls 22 control the motor speed as described more fully hereinbelow to provide the infusion device with the desired output.

In a preferred construction, the infusion device 15 is a peristaltic pump of the type disclosed in Application Serial No. 661,032 entitled Continuous Delivery Peristaltic Pump and filed on October 15, 1984. Such an infusion pump has a normal delivery pattern 25 which, in this example, is essentially constant as shown by the flat portions of the pump delivery curve of Fig. 2. This is the result of accelerating through the deadband of the peristaltic pump. The curve of Fig. 2 is somewhat idealized in that the preferred infusion pump provides periodic short spikes and valleys of exceedingly short duration; however, these are sufficiently insignificant so that the normal delivery patter of the pump can be considered as essentially constant, although a constant flow rate during the normal delivery pattern is not required.

The pump controls 22 periodically, and/or on demand, increase the speed of the stepping motor 21 to cause the infusion pump 20 to provide the test pulse 19 which, in the illustrated embodiment of Fig. 2, is in the form of an essentially square wave having a duration of approximately four seconds. As described more fully in Bobo Patent No. 4,648,869 the infusion rate, and hence the volume delivered, during the test pulse preferably varies with the selected infusion rate for the infusion device 15. However, the duration of the test pulse 19 may be constant for all selected infusion rates. Selection of the infusion rate also results in selection of the associated flow rate for the test pulse 19. In this regard, the pump controls 22, as is common for infusion devices of this type, are programmable to enable the attendant to select or punch in a desired or selected infusion rate.

The pump controls 22 reduce the speed of the stepping motor 21 just before and just after each test pulse 19 to cause the infusion pump 20 to provide separating regions, which in this embodiment, are leading and trailing infusion valleys 27 and 29, respectively, contiguous to, and on opposite sides of, the test pulse 19. The valleys 27 and 29 are square waves of short duration during which the infusion rate is reduced sufficiently to wholly or partially compensate for the increased infusion rate which takes place during the test pulse 19. Preferably, the valleys 27 and 29 reduce the total flow by the same amount that the test pulse increases it so that the average or net effect across the valleys 27 and 29 and the test pulse 19 is an infusion rate equal to the rate represented by the normal delivery pattern 25. For example, each of the valleys 27 and 29 may have a duration which is twice as long as the duration of the test pulse 19, with such duration being 8 seconds in this embodiment and constant for all selected infusion rates. The test pulse 19 and the valleys 27 and 29 constitute an altered pattern of flow.

Test pulses can be provided in various different ways, and additional examples of test pulses, which can be distinguished from the normal delivery pattern, are shown in Figs. 2A-2E. Portions of the curves shown in Figs. 2A-2E corresponding to portions of the curve shown in Fig. 2 are designated by corresponding reference numerals followed by the letter "a", "b", "c", "d", and "e", respectively.

In Fig. 2A, the test pulse 19a is separated from the normal delivery pattern 25a by leading and trailing valleys 27a and 29a in much the same manner as disclosed in Fig. 2. However, the infusion rate during the test pulse 19a is the same as the infusion rate during the normal delivery pattern 25a. Although the infusion rates during the valleys 27a and 29a can be "0" or negative, preferably, the infusion rates during these times are positive. Also, although the infusion rates during the valleys 27a and 29a can be different, preferably, they are essentially the same.

In Fig. 2B, the test pulse 19b is negative, i.e., the infusion pump 20 is reversed to create the infusion pulse. Although the infusion rate during the valleys 27b and 29b may be either positive or negative, in this embodiment, they are essentially "0."

In Fig. 2C, a plurality of test pulses 19c is provided in relatively rapid succession before the infusion rate returns to the normal delivery pattern 25c. In this event, the valleys 27c and 29c between adjacent test pulses 19c constitute both trailing and leading valleys as shown.

In Fig. 2D, the separating regions 27d and 29d are not distinguishable from the normal delivery pattern 25d, and so the altered pattern of delivery consists only of the test pulse 19d. This can be contrasted with the embodiments described above in which the altered pattern comprises both the leading and trailing

supplied by the conduit means to the patient; and
means responsive to the pressure wave response for detecting if fluid is being improperly supplied by the conduit means to the patient.

41. An infusion system as defined in claim 40 wherein said first means includes means for comparing a function of the pressure of the fluid in the conduit means during the normal delivery pattern to a threshold to ascertain if pressure conditions in the conduit means are suitable for detecting if fluid is being improperly supplied by the conduit means to the patient.

42. An infusion system as defined in claim 41 wherein said function of the pressure equals B1 + K(B2) where B1 is the baseline pressure at an instant prior to the test pulse, K is a constant and B2 is the rms value of a plurality of segments of the baseline pressure prior to the test pulse and with at least one of said segments being prior to said instant.

43. An apparatus for determining if fluid is being properly supplied through a fluid delivery system to a patient, said apparatus comprising:
means for delivering fluid through the delivery system so as to create a pressure wave response in the delivery system;
first means responsive to the pressure in the delivery system when the pressure wave response is not present to ascertain if pressure conditions in the delivery system are suitable for detecting if fluid is being improperly supplied by the delivery system to the patient; and
means responsive to the pressure wave response for detecting if fluid is being improperly supplied by the delivery system to the patient.

44. An apparatus as defined in claim 43 wherein said first means includes means for comparing a function of the pressure of the fluid in the delivery system during the normal delivery pattern to a threshold to ascertain if pressure conditions in the delivery system are suitable for detecting if fluid is being improperly supplied by the delivery system to the patient.

45. An apparatus as defined in claim 44 wherein said function of the pressure equals B1 + K(B2) where B1 is the baseline pressure at an instant prior to the test pulse, K is a constant and B2 is the rms value of a plurality of segments of the baseline pressure prior to the test pulse and with at least one of said segments being prior to said instant.

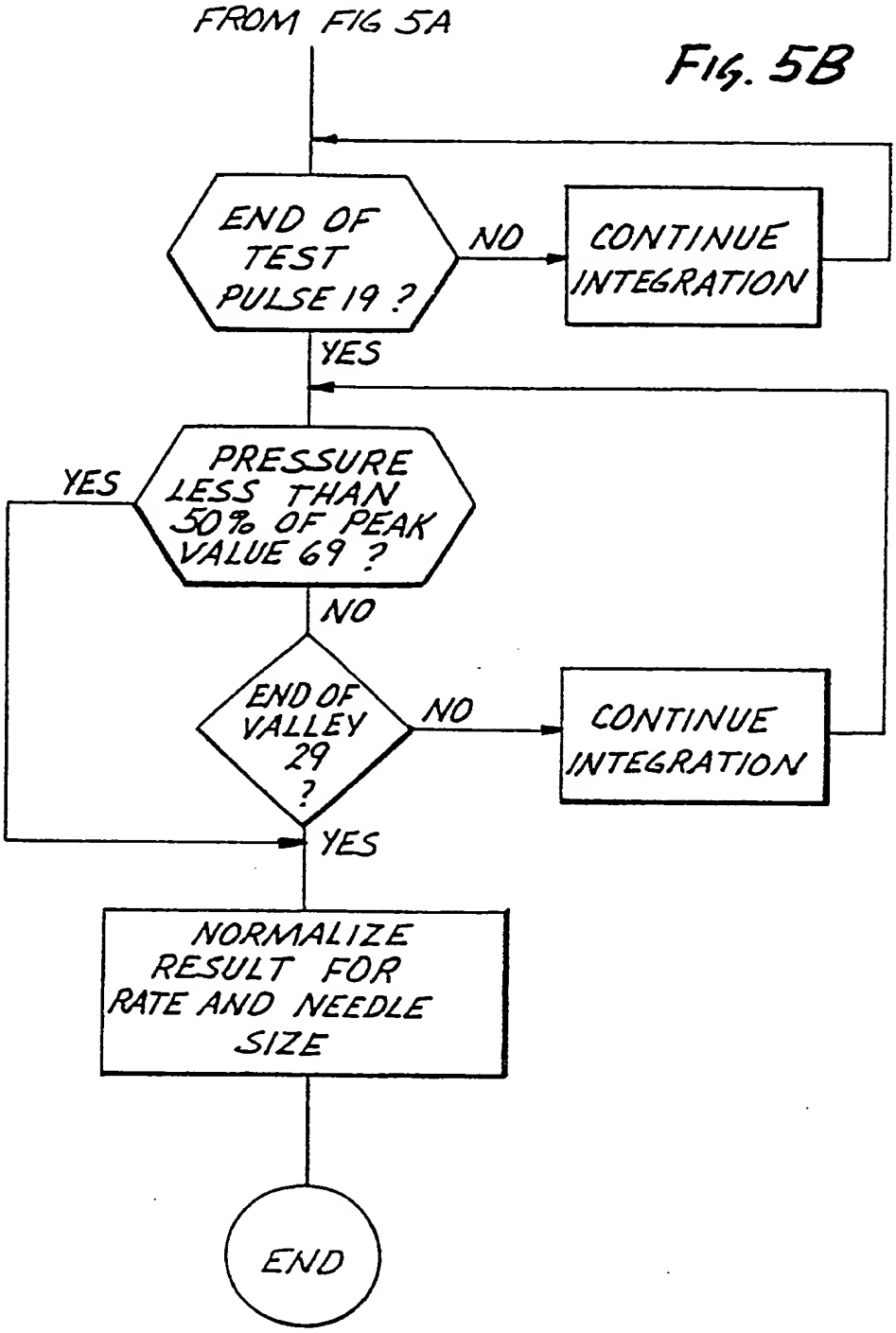
FROM FIG 5A
END OF TEST PULSE 19 ?
NO
CONTINUE INTEGRATION
YES
PRESSURE LESS THAN 50% OF PEAK VALUE 69 ?
YES
NO
END OF VALLEY 29 ?
NO
CONTINUE INTEGRATION
YES
NORMALIZE RESULT FOR RATE AND NEEDLE SIZE
END

Fig. 5B

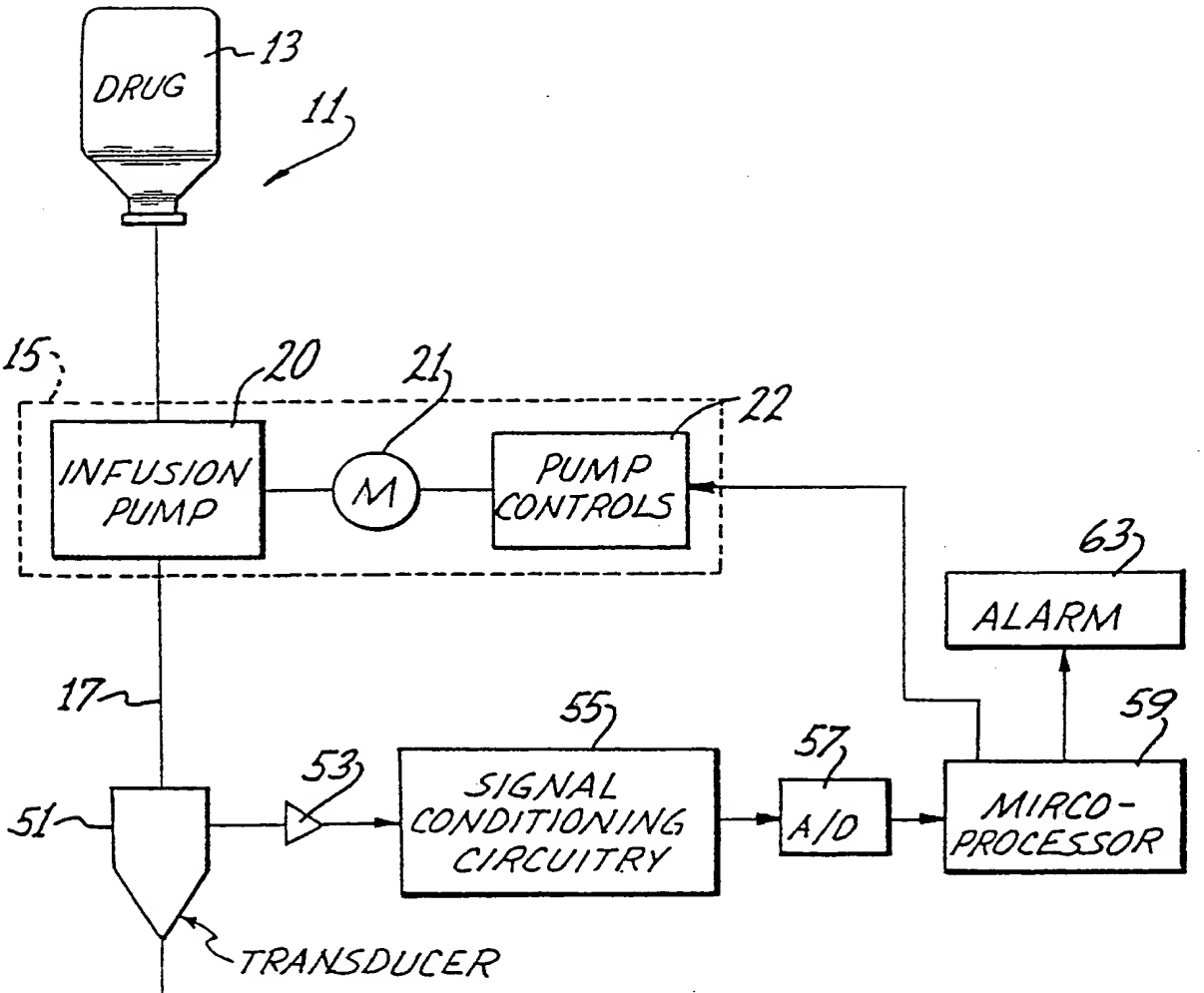
DRUG
13
11
15
20
21
22
INFUSION PUMP
M
PUMP CONTROLS
63
ALARM
17
55
59
53
57
51
SIGNAL CONDITIONING CIRCUITRY
A/D
MIRCO-PROCESSOR
TRANSDUCER

Fig. 1

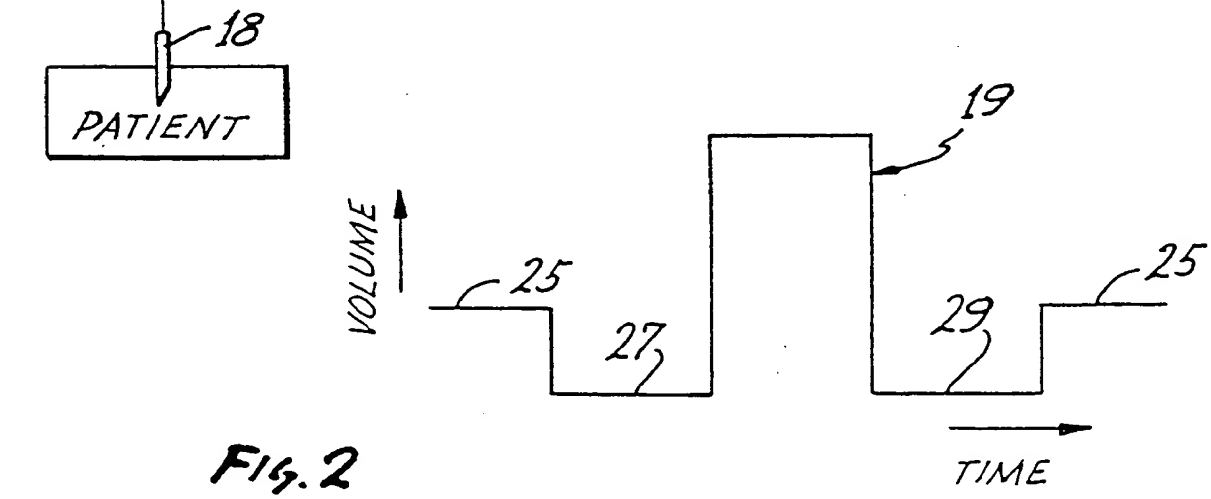
18
PATIENT
19
VOLUME
25
27
29
25
TIME

Fig. 2

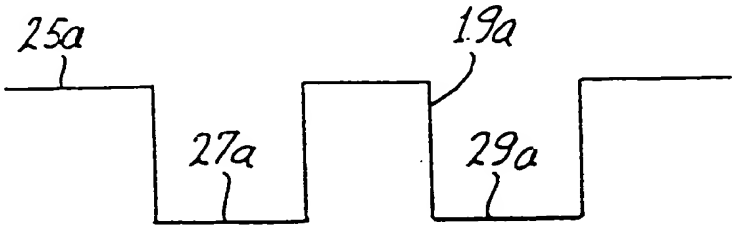

FIG. 2A

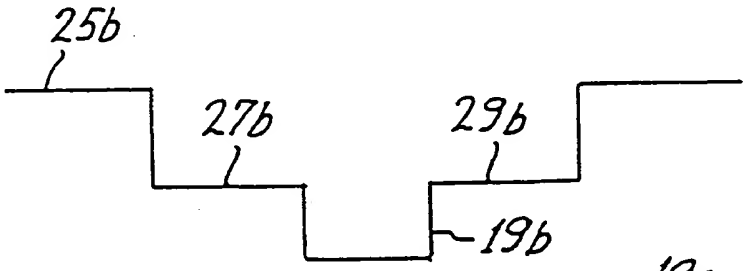

FIG. 2B

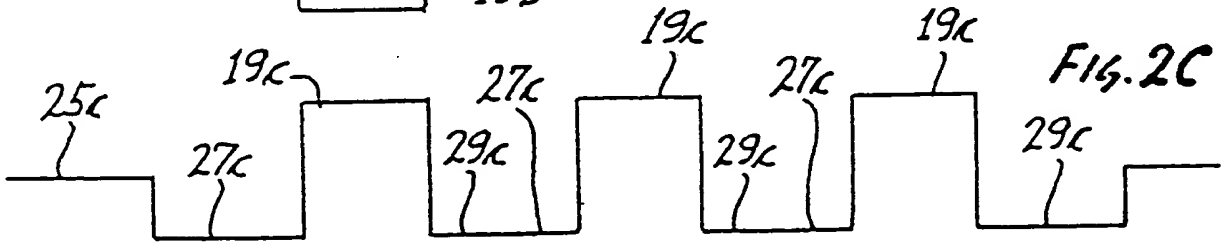

FIG. 2C

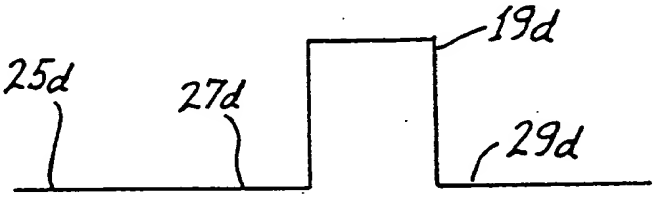

FIG. 2D

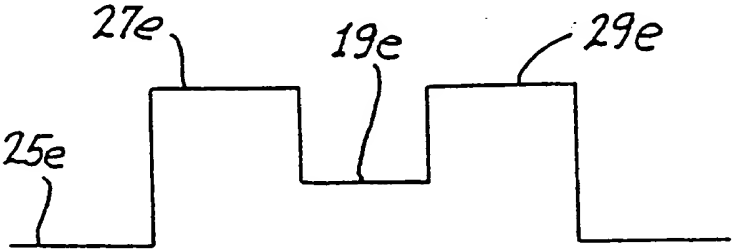

FIG. 2E

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application number: EP 89 30 2006

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X,D	US-A-4 648 869 (BOBO) * Abstract; column 4, lines 16-43; column 5, lines 3-65; figures *	1,2,7, 8,13	A 61 M 5/14 F 04 B 51/00
Y		29,30	
A		31	
	--		
Y,D	EP-A-0 248 633 (IVAC CORP.) * Page 4, lines 8-32; page 4, line 65 - page 5, line 6; figures * & US-A-4 710 163	29,30	
A		1,2,7, 8,13,31	
	--		
A	EP-A-0 121 931 (IVAC CORP.)		TECHNICAL FIELDS SEARCHED (Int. Cl.4)
	--		
	./.		A 61 M F 04 B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.

Claims searched completely: 1-10,13,22,23,27-31,43

Claims searched incompletely:

Claims not searched: 15,25,33,36,39

Reason for the limitation of the search:

Certain claims are obscure because they are dependent on others which have been annuled due to non-payment of fees.

Place of search	Date of completion of the search	Examiner
The Hague	27-09-1989	CLARKSON

CATEGORY OF CITED DOCUMENTS

- X : particularly relevant if taken alone
- Y : particularly relevant if combined with another document of the same category
- A : technological background
- O : non-written disclosure
- P : intermediate document
- T : theory or principle underlying the invention
- E : earlier patent document, but published on, or after the filing date
- D : document cited in the application
- L : document cited for other reasons
- & : member of the same patent family, corresponding document

EPO Form 1505.1 03.82

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application number

EP 89 30 2006

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int Cl 4)
A	WO-A-8 705 224 (KAMEN) --		
A	EP-A-0 248 632 (IVAC CORP.) -----		
			TECHNICAL FIELDS SEARCHED (Int Cl 4)

European Patent Office

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ All claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for all claims.

☒ Only part of the claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid.

namely claims: 1-10,13,15,22,23,25,27-31,33,36,39,43

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirement of unity of invention and relates to several inventions or groups of inventions.

namely:

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid.

namely claims:

☐ None of the further search fees has been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.

namely claims: